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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,719	10/10/2001	Frederick M. Ausubel	00786/361003	1062
21559	7590	06/24/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			NAVARRO, ALBERT MARK	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,719

Applicant(s)

AUSUBEL ET AL.

Examiner

Mark Navarro

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 22-53 is/are pending in the application.
4a) Of the above claim(s) 1, 44-47 and 50-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 48, 49 and 53 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Applicants amendment filed April 12, 2004 has been received and entered. Claims 2-43 have been canceled and new claim 53 has been added. Accordingly claims 1, and 44-53 are pending in the instant application, of which claims 1, 44-47, and 50-52 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 48-49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Additionally this rejection is applied to newly added claim 53.

Applicants are asserting that the scope of the claims is now limited to highly homologous sequences (90% identity) that share structural similarity and common attributes with the disclosed sequence. Applicants have further enclosed Exhibit A which shows the predicted start and stop codons of the polypeptide encoded by SEQ ID NO: 252. Applicants assert that while multiple start codons and stop codons are in fact present in SEQ ID NO: 252, one skilled in the art would immediately recognize that SEQ ID

NO: 252 encodes one open reading frame that encodes a full length polypeptide.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the scope of the claims is now limited to highly homologous sequences (90% identity) that share structural similarity and common attributes with the disclosed sequence. However, adequate written description requires both structure and function to identify members of a genus. While Applicants have attempted to comply with the structure requirement (90% identity), the identity of this protein still remains nebulous. Again given the multiple start and stop codons one of skill in the art would be unable to determine which protein is referred to as being encoded by SEQ ID NO: 252. Furthermore, even if the identity of the protein could be determined, Applicants specification provides no function of the 90% identical proteins to identify members of the genus.

Finally Applicants have further enclosed Exhibit A which shows the predicted start and stop codons of the polypeptide encoded by SEQ ID NO: 252. Applicants assert that while multiple start codons and stop codons are in fact present in SEQ ID NO: 252, one skilled in the art would immediately

recognize that SEQ ID NO: 252 encodes one open reading frame that encodes a full length polypeptide. However, Applicants predicted start and stop codons are not described in the originally filed specification. Thus any attempt to identify the proper start and stop codons at this point are deemed to be new matter, absent a specific disclosure pointing out the precise start and stop codons in the originally filed specification. It is noted that Applicants start codon (Exhibit A) suggests that the start codon begins at nucleotide numbers 19-21, however there is also a start codon at positions 7-9. Why would one of skill in the art "immediately recognize" that SEQ ID NO: 252 encodes one open reading frame that encodes a full length polypeptide? Given that multiple start and stop codons are present, without precise guidance as to which specific start and stop codons are to be used for a single protein, no such recognition can take place.

Claims 48-49 and 53 are directed to a substantially pure polypeptide comprising an amino acid sequence that has a least 90% identity to the amino acid sequence of a polypeptide encoded by SEQ ID NO: 252, or is identical to the amino acid sequence of a polypeptide encoded by SEQ ID NO: 252.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 252 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by the substantially identical polypeptides which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Furthermore, Applicants have claimed a protein encoded by SEQ ID NO: 252 without identifying a full length open reading frame. The isolated DNA strand (SEQ ID NO: 252) has multiple reading frames, Applicants have not identified a start codon or a stop codon of the protein being claimed. Consequently, Applicants have not identified a function which

identifies members of the genus, since the structure of the protein cannot be fully determined without a start and stop codon for the full length protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record, as well as the reasons set forth above this rejection is maintained.

The following new grounds of rejection are applied to the claims:

Claim Objections

2. Claim 48 is objected to because of the following informalities: Claim 48 recites "... has a least 90% identity.... An obvious typographical error, the phrase should recite "has at least 90% identity." Appropriate correction is required.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
June 23, 2004